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U. S. Department of Energy

Environmental Management Consolidated Audit Program

Module 8

Checklist for Special Biological Analysis Data Quality

Audit ID: _____

Item	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed/Audit Notes
8.1	**Quality Assurance Documents**		
8.1.1	The laboratory has implemented a Laboratory Quality Assurance Plan (QAP) complying with DOE Order 414.1A that is issued and maintained as a controlled document. *(ICPT BOA Attachments B & C Criterion 1, Program)*		
8.1.2	The QAP defines the laboratories policies and its commitment to: • ethical standards • client confidentially • good laboratory practices • client services *(ICPT BOA Attachments B & C, Criterion 1, Program)*		
8.1.3	The QAP includes a listing of certifications and accreditations or a reference to the locations of such a list if not included in the QAP. *(ICPT BOA Attachments B & C, Criterion 1, Program)*		

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8.1.4	The QAP describes the: • organizational structure • functional responsibilities • levels of authority • interfaces for those managing, performing and assessing work. *(ICPT BOA Attachments B & C, Criterion 1, Program)*		
8.1.5	The QAP is accessible to all laboratory personnel and they are aware of its location. *(ICPT BOZ Attachments B & C, Criterion 1, Program)*		
8.1.6	The QAP includes an organizational chart delineating that QA personnel operate independently from cost and schedule functions and report directly to the highest level of laboratory management. *(ICPT BOA Attachments B & C, Criterion 1, Program)*		
8.2	**Quality Assurance Management**		

Item	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed/Audit Notes
8.2.1	General Quality Assurance Management responsibilities include: • oversight of corrective actions • oversight of Performance Evaluation (PE) analysis • report • report to management • internal audits • review of Statements of Work (SOW) and Standard Operating Procedures (SOPs) *(ICPT BOA Attachments B & C, Criterion 3)*		
8.2.2	A quality assurance officer has been designated in writing, who is empowered to: • stop unsatisfactory work • prevent reporting results from an out of control measurement system • initiate and monitor corrective action procedures • revise, control and distribute the QAP. *(ICPT BOA Attachments B & C, Criterion 1)* *(Recommended Laboratory Practices)*		
8.3	**Performance Evaluation Programs**		

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8.3.1	The laboratory must demonstrate successful participation for a minimum of one year in relevant performance evaluation program or round robin testing program. *(ICPT BOA, Attachments B & C, Selected Management Requirements, Section 2)*		
8.3.2	• The laboratory documents the root cause and corrective action for failed PE samples. *(ICPT BOA, Attachments B & C, Criterion 3)*		
8.4	**Personnel Training and Qualification**		
8.4.1	The laboratory organization possesses well-defined and documented roles and responsibilities for each position. *(ICPT BOA Attachments B & C, Criterion 1)*		
8.4.2	The laboratory has a documented training program indicating the professional requirements for performing certain operations. *(ICPT BOA Attachments B & C, Criterion 1)*		

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8.4.3	The laboratory maintains records of indoctrination and training in the form of: • attendance sheets • training logs • personnel training records • a description of the training and indoctrination *(ICPT BOA Attachments B & C, Criterion 2)*		
8.4.4	Documentation is maintained indicating training in: • technical skills • laboratory analytical methods • QC procedures • Safety policies • Waste management practices • Radiation worker training *(ICPT BOA Attachments B & C, Criterion 2)*		
8.4.5	The laboratory has a written analyst proficiency evaluation policy that provides a means to gauge and document the continuing competence of experienced individuals, as well as specifying additional training and documentation practices applicable to all personnel. *(ICPT BOA Attachments B & C, Criterion 2)*		

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8.4.6	The following personnel criteria have been satisfied: • Management has established personnel qualifications for each position • Management has established training requirements for each project person • Personnel qualifications should be reviewed and documented periodically *(ICPT BOA Attachments B & C, Criterion 2)*		
8.5	**Quality Control Systems**		
8.5.1	The laboratory has established a system to identify, document, correct, and prevent quality problems. *(ICPT BOA Attachments B & C, Criterion 3)*		
8.5.2	There has been documented review by management to assess the effectiveness of the quality improvement system. *(ICPT BOA Attachments B & C, Criterion 3)*		

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8.5.3	The laboratory has established a "Non-Conformance System" to identify problems, out-of-control events and issues that are not part of scheduled assessments. *(ICPT BOA Attachments B & C, Criterion 3)*		
8.5.4	A corrective action process has been implemented which determines: • events leading to the adverse condition • technical activities associated with the problem • generic implications of the problem • extent to which similar problems have occurred • assignment of personnel to corrective action • documentation of corrective action plan • effectiveness of corrective actions • actions taken to preclude recurrence *(ICPT BOA Attachments B & C, Criterion 3)*		
8.5.5	Written procedures are in place for the notification to affected organizations of nonconforming items. *(ICPT BOA Attachments B & C, Criterion 3)*		

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8.5.6	The laboratory has a system that tracks corrective actions to completion. *(ICPT BOA Attachments B & C, Criterion 3)*		
8.6	**Documents and Records**		
8.6.1	Laboratory activities affecting quality are defined in documented instructions or procedures which are: • distributed in a controlled manner • periodically reviewed and updated • available to all laboratory personnel • retained in the laboratory's archives *(ICPT BOA Attachments B & C, Criterion 4)*		
8.6.2	The laboratory has established a minimum frequency for review of controlled documents and procedures. *(ICPT BOA Attachments B & C, Criterion 4)*		

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8.6.3	Standard Operating Procedures are in place for (but not limited to) the following areas: • Sample tracking and COC procedures • Sample preparation (including subsampling) • Sample storage and security • Proper sample disposition • Prevention of sample contamination • Facility security • Data reduction, verification, and reporting • Acceptance criteria (e.g., QC limits, calibrations, etc.) • Document control • Data packages review prior to submittal • Shipment of deliverables • Records disposition • Preparation and traceability of standards • Catastrophic failure of a refrigerator, freezer unit • Glassware cleaning • Equipment maintenance • Qualification of personnel and training *(ICPT BOA Attachments B & C, Special QA Requirements, Section G.8)*		
8.6.4	A system is in place to ensure that quality records are legible, accurate, complete, and appropriate to the work accomplished. *(ICPT BOA Attachments B & C, Criterion 4)*		

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8.6.5	Corrections to documents that will become quality records are made by drawing one line through the error, initialing and dating the error, and justifying the correction (if not self-explanatory). *ICPT BOA Attachments B & C, Criterion 4)*		

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8.6.6	The laboratory has a procedure delineating the records control system that includes: • specification for items, data, and processes of which records are to be controlled • requirements for the preparation, review, approval, and maintenance of records to accurately reflect completed work and fulfill statutory requirements • requirements and responsibilities for the record transmittal, distribution, change, retention, protection, preservation, traceability retrieval and disposal • verification that records are legible and are in agreement with the transmittal document • requirements for access to and control of files • procedures for the control, and client confidentiality accountability of records removed from the storage location • procedures for filing of supplemental information and disposal of superseded records • storage of records in a manner approved by the organizations responsible for the records • replacement, restoration, and substitution of lost or damaged records • procedures for data correction, which includes how corrections are made and establish who is authorized to change or correct data *(ICPT BOA Attachments B & C, Criterion 4)*		

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8.6.7	The laboratory has procedures in place to validate non-standardized methods, laboratory designed/developed methods used outside their intended range and amplifications of standardized methods to confirm that the methods are fit for the intended use. The procedures include: • scope • description of the type of item to be tested or calibrated • parameters or quantities to be determined • apparatus, equipment, reference standards and reference materials is required • environmental conditions required and any stabilization period needed • description of the procedure, including affixing identification marks, handling, transporting, storing and preparing of items, checks to be made before the work is started, checking that the equipment is working properly and, where required, calibrating and adjusting the equipment before each use, method of recording the observations and results, an safety measure to be observed • criteria and/or requirements for approval/rejection • data to be recorded and method of analysis and presentation • uncertainty or procedure for estimating uncertainty *(ISO 17025, Section 5.4.4 and 5.4.5; and ICPT BOA Attachments B & C, Criterion 5)*		

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8.6.8	The laboratory has procedures for reviewing and documenting changes made to data after report preparation that ensures traceability of updates. *(ICPT BOA Attachments B & C, Criterion 4)*		
8.6.9	Records of data and other technical information are maintained in environmentally secure controlled access storage, which shall protect the records from unauthorized access or damage. Alternatively, the laboratory stores duplicate records at a different location. *(ICPT BOA Attachments B & C, Criterion 4)*		
8.7	**Work Process**		
8.7.1	A Standard Operating Procedure is in place for reagent and deionized water production which includes (at a minimum): • preventative maintenance of water purification equipment • control criteria • corrective action processes for out-of-spec water *(ICPT BOA Attachments B & C, Special QA Requirements, Section B.4)*		

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8.7.2	• The conductivity and/or resistivity of the water from the purification system is monitored daily and the results are recorded in a logbook. *(ICPT BOA Attachments B & C, Special QA Requirements, Section B.4)*		
8.7.3	The chlorine content of the DI water is checked each day and documented each day of testing.		
8.7.4	Sample glassware and containers are either designated as disposable or cleaned according to recommended procedures. *(ICPT BOA Attachments B & C, Special QA Requirements, Section B.1)*		

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8.7.5	A copy of the laboratory-specific Standard Operating Procedure (SOP) for glassware cleaning is posted in the glassware cleaning area of the laboratory. The sample preparation area must be kept clean to avoid contamination or cross-contamination. *(ICPT BOA Attachments B & C, Special QA Requirements, Section B.2)*		
8.7.6	The temperature of sample storage refrigerators will be controlled and the temperature measured and documented each day. *(ICPT BOA Attachments B & C, Special QA Requirements)*		

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8.7.7	The laboratory maintains hard copy laboratory notebooks that detail: • the sample bottle preparation and analytical work, including the analyses being performed • samples being analyzed • procedures used • readings taken • calculations performed • analytical results • any observations noted during analysis *(ICPT BOA Attachments B & C, Special QA Requirements, Section G.7)*		
8.7.8	Standards and reagents materials shall be stored separately from samples and standards protected in a controlled cabinet or refrigerator. *(ICPT BOA Attachments B & C, Criterion 5)*		
8.7.9	• Reagent grade or higher purity chemicals must be used. Reagents are checked prior to use and the supporting documentation of the checks shall be filed in a manner that can be easily retrieved. *(ICPT BOA Attachments B & C, Criterion 5)*		

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8.8	**Aquatic Toxicity Testing**		
8.8.1	The culturing and testing of organisms is performed in a separately designed laboratory area, isolated from the chemical testing of the laboratory.		
8.8.2	The climate is controlled to 20°C +/- 1, where all fish and Daphnia culturing, as well as where all acute testing is performed.		
8.8.3	The Ceriodaphnia are cultured and the chronic tests performed in a room that is controlled at 25°C +/- 1.		
8.8.4	Laboratory and test lighting is fluorescent lighting on a 16:8 (Light:Dark) timer cycle.		
8.8.5	The bioassay samples must be initially used within 36 hours of collection, after the initial use it can be reused for up to 72 hours.		
	Pimephales promelas (Fathead Minnow)		

Item	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed/Audit Notes
8.8.6	The pH of the Pimephales promelas (Flathead Minnow) Fish Tanks is maintained at 7.00 and the pH is adjusted using a sodium bicarbonate solution.		
8.8.7	The temperature of the Fathead Minnow tanks is maintained at 24-26°C.		
8.8.8	The ammonia of the Fathead Minnow tanks is monitored and controlled.		
8.8.9	Twice each day, the tiles of the breeder tanks must be checked for eggs.		
8.8.10	The temperature of the fry is maintained at ambient lab temperature, 20°C +/- 1.		
	Daphnia pules and Ceriodaphnia dubia (Daphania and Ceriodaphnia)		
8.8.11	Daphnia cultures are maintained in 0.5 liter of culture medium. Five to eight cultures are maintained in borosilicate beakers at 20°C +/- 1.		

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8.8.12	Cerodaphnia mass cultures are housed in 0.5 liters of culture medium and are maintained at 25°C +/- 1.		
8.8.13	One a week, fresh cultures are started by transferring 10 to 15 young adults to fresh culture medium.		
	Test Conditions		
8.8.14	Samples which arrive at the laboratory that are supersaturated once warned to test temperature must be stripped of excess Dissolved Oxygen (DO) by vigorously shaking the sample.		
8.8.15	If a sample is found to have a residual chlorine >0.1 mg/L, it is to be dechlorinated only if the permit has included chlorine as a parameter have a period to achieve compliance. (Otherwise the sample must not be dechlorinated.) Dechlorination is performed by adding sodium thiosulfate to the sample.		
8.8.16	If the pH of the sample is not within 6 to 9, it must be adjusted using nitric acid or sodium hydroxide.		

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8.8.17	Clients are notified if any sample falls outside of its anticipated range for pH or Chlorine.		
8.8.18	When D.O. levels in the fathead minnows reaches 4.0 mg/L, aeration must be initiated at a rate of less than 100 bubbles per minute in each test vessel.		
	Daphina pulex acute protocol		
8.8.19	The effluent and diluent are warmed to 20°C +/- 1 prior to the start of the test.		
8.8.20	Twenty-four hours prior to the start of the test, adults are removed from the stock cultures of Daphnia pulex. The adults which appear to be carrying neonates should be chosen for the test.		
8.8.21	The neonates that have been released during the last twenty-four hours are removed from the test beaker.		

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8.8.22	At twenty-four (24) and forty-eight (48) hours, the temperature is measured in one replicate of each concentration and recorded on the bench sheet as well as time and initials of who checked the test.		
8.8.23	At forth eight (48) hours, after counting final survival, solutions are consolidated and the temperature, C.O., pH, and conductivity are measured and recorded.		
8.8.24	The time and date of test conclusion is documented.		
8.8.25	Control mortality cannot exceed 10% in order for the test to be valid.		
8.8.26	Acute tests must be checked +/- 2 hours from when they are initially setup and they must end +/- 1 hour from when they are setup.		
	Fathead minnow acute protocol		
8.8.27	The effluent and diluent are warmed to 20°C +/- 1 prior to the start of the test.		

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8.8.28	Two replicates for each concentration are tested.		
8.8.29	The D.O., pH, temperature and conductivity are taken and documented at the start of the test.		
8.8.30	Fish which are less than 14 days old are within twenty four hour of each other are gently netted and removed their culture tanks and then pipetted into a glass culture dish. A total of 10 fish are added to each dish.		
8.8.31	The test is started when the last fish have been added and the time id documented.		
8.8.32	At twenty-four (24) hours, the D.O., and pH of each concentration are measured and documented. The number of living fish are counted and documented for each vessel. The dead fish are removed from the vessel.		
8.8.33	The test is concluded at end of required time (48-96 hours).		
8.8.34	At the conclusion of the test, temperature, pH, D.O., conductivity and final mortality are checked.		

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8.8.35	Data is evaluated using the appropriate statistical analysis. (EPA's Probit Analysis program if necessary or if applicable, the Spearman-Karber method, or two cycle, semi-log graphing are used.)		
8.8.36	Control mortality must not exceed 10% in order for the test to be valid.		
8.8.37	25°C +/- 1		
	Ceriodaphnia chronic protocol		
8.8.38	The effluent and diluent are warmed to 25^0 C +/- 1 prior to the start of the test.		
8.8.39	The evening before a test is to be initiated, Ceriodaphnia brood trays are checked and those beakers which contain new neonates are noted. At midnight the brood vessels are checked again and any new neonates are noted. The morning of the test, the brood vessels are checked again and any neonates are noted. Each check should be within 8 hours of the previous one.		

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Item	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed/Audit Notes
8.8.40	For some states, brood trays must have records of mortality and reproduction.		
8.8.41	Mix all necessary dilutions using warmed effluent and diluent.		
8.8.42	When all dilutions are mixed, the pH, temperature, D.O., and conductivity of each concentration are measured and documented.		
8.8.43	When all the dilutions are poured, the previously identified neonates can be transferred.		
8.8.44	The test is changed by mixing new dilutions are previously prepared. Measure and document the new temperature, pH, D.O., and conductivity of each dilution, adjusting the temperature as needed.		
8.8.45	The adults are removed from the old beakers and gently transferred to the corresponding new beakers.		

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Item	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed/Audit Notes
8.8.46	If neonates, are present in the old beaker, they are left and not transferred. After all the adults are transferred, neonates are counted and adult survival and neonates are recorded.		
8.8.47	All of the old beakers are consolidated into their representative dilution beaker where final pH, D.O, temperature and conductivity are measured and recorded.		
8.8.48	The test ends when at least 60% of all the control females had their third brood of neonates, with the total of all three broods averaging 15 or greater. (Note: An average production of 14.8 cannot be rounded up to satisfy the 15.0 requirement.)		
8.8.49	Consolidate the different test vessels into their representative dilution beaker and measure and document the temperature, pH, D.O., and conductivity.		
8.8.50	Statistical analysis is performed using Toxstart to determine a 48-hour LC50 and NOEC's for survival and reproduction where applicable. (NOEC is the lowest of the two endpoints, survival and rejection and NOEC cannot be reported as a greater than value.)		

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	Fathead chronic protocol		
8.8.51	The effluent and diluent are warmed to 25^0 C +/- 1 prior to the start of the test.		
8.8.52	In the morning, take down all fry which have hatched. Six hours later, removed tiles from any hatching jars which have new fry. These are the fry which will be used in setting up the Chronic test on Day 2. These fry are then placed into the environmental room to allow a period of acclimation. (Fry are hatched at 20^0 C +/- 1)		
8.8.53	A minimum of three replicates and a minimum of five concentrations, plus a control must be used.		
8.8.54	Prepare concentrations by a factor of 0.5, ie: Control, 6.25%, 12.5%, 25%, 50%, and 100%.		
8.8.55	The required temperature must remain at 25^0 C +/- 1.		
8.8.56	The pH, D.O., temperature and conductivity are measure of each concentration at the start of the test.		

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8.8.57	If D.O. in any of the concentrations falls below 4.0 mg/L, then aeration must be set up for all vessels at a rate of <100 bubbles per minute to continue for the duration of the test.		
8.8.58	Run appropriate parameters on sample and dilution water: residual chlorine, alkalinity and hardness. Also if suspected to be high, ammonia can be tested. Also, all new samples which are obtained for test renewal and new batches of dilution water must have chemical parameters before use. (Alkalinity, Hardness and Chlorine)		
8.8.59	When preparing fish, fish from three different spawnings must be used.		
8.8.60	A minimum of ten fish per vessel should be used (15 is recommended).		
8.8.61	The test is renewed at 24-hour intervals.		
8.8.62	Within two hours of test initiation, warm dilution and effluent to 25^0 C +/- 1. Take pH, D.O., temperature and conductivity and document.		

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8.8.63	Using a small siphon, drain 90% of solutions form each test vessel and discard. Remove all dead fish and debris from the bottom of each vessel and count the number of surviving fish.		
8.8.64	Prepare new dilutions and check pH, D.O., temperature and conductivity of each. Place vessels back in environmental chamber and repeat procedure at 24-hour intervals.		
8.8.65	After 168 hours, final pH, D.O., and temperature are taken. 90% of the each vessel's solution is drained and discarded.		
8.8.66	Final mortality is checked and all surviving fish are sacrificed using alcohol, by replicate, to be weighed immediately in 1 cm square foil weigh boats.		
8.8.67	Final control mortality can not exceed 20% and control per fish dry weight must be 0.25 mg minimum for valid results.		
	Reference Toxicant Tests		

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8.8.68	QA tests are run monthly for Acutes and quarterly for Chronics. The effluent concentration of Cd is generally in the following ranges for each species test: • Dalphnia acute 0.013-0.195 mg/L • Ceriodaphnia 0.017-0.085 mg/L • Fathead Acute 0.001-0.0279 mg/L (48 and 96 hour combined) • Ceriodaphnia chronic 0.000-0.017 mg/L • Fathead chronic 0.000-0.016 mg/L		

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